

REMARKS

Claims 21-35 are pending. By this paper, Claims 21, 22, 24, 25 and 34 have been amended. The amendments add no new matter. Claims 21-35 are hereby presented for further consideration in view of the following remarks.

Rejections under § 103(a) over Moe et al. in view of Verona

Claims 21-23, 28, and 31-35 were rejected as being obvious over Moe et al. (U.S. Patent Publication 2003/0023302) in view of Verona (U.S. Patent No. 3,983,581). Claims 24-26 are rejected as being obvious over Moe et al. and Verona, further in view of Rosen (U.S. Patent No. 4,345,340). Claim 27 is rejected as being obvious over Moe et al. and Verona, further in view of Gupta (U.S. Patent No. 4,851,000). Claims 29-30 are rejected as being obvious over Moe et al. and Verona, further in view of Pavcnik (U.S. Publication No. 2001/0039450).

Applicant respectfully submits that the present rejections are essentially the same as the previous rejection based on a combination of Moe et al. and Angell (alone or further in view of the additional references noted above), which Applicant previously overcame in the Response filed July 13, 2009 (See also the Interview Summary dated July 7, 2009). In the present rejection, the Examiner has merely replaced the Angell reference with the Verona reference. Applicant submits that Verona includes no teachings overcoming the deficiencies of the previously-cited Moe et al. and Angell references, and maintains that the cited art of record fails to disclose an "an aortic valve obtained from an animal... and at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of said aortic valve." Nevertheless, in order to expedite prosecution of the present application, Applicant has amended the claims as described below.

Independent Claim 21

Independent Claim 21 has been amended to recite "a substantially intact aortic valve." As Examiners Schillinger and Isabella agreed during the interview, the combination of Moe et al. and Verona does not teach or suggest a "biological prosthesis comprising a substantially intact aortic valve obtained from an animal, through which substantially intact aortic valve blood flows in a single direction, the substantially intact aortic valve having a tubular outer wall, and at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of

said substantially intact aortic valve, the rod penetrating the thickness of the tubular outer wall of said substantially intact aortic valve,” as recited in independent Claim 21.

As noted above, the references cited in the present rejections are essentially the same as those cited in the rejection which Applicants overcame with the Response filed July 13, 2009 (See also the Interview Summary dated July 7, 2009). In the current rejection the Examiner has substituted the Verona reference for the previously cited Angell reference. With respect to Verona, as discussed during the April 29, 2010 interview, this reference teaches methods for using corneal tissue from a fish eye to form cusps of a bioprosthetic valve, and does not disclose or suggest at least “a biological prosthesis comprising a substantially intact aortic valve obtained from an animal” as recited in amended Claim 21.

With respect to Moe, as discussed during the June 30, 2009 interview and as also attested to in the Declaration by Dr. Norman Jaffe submitted on December 29, 2008, one of skill in the art would not have considered modifying the device of Moe et al. by using natural tissue, instead of the polymeric material taught by Moe et al., because the modified device would be expected to fail. (See December 29, 2008 Declaration at Paragraph 8). The Office Action states, however, that “the prior art does not specifically state that natural tissues cannot be used, nor would the device of Moe et al. be destroyed with a natural tissue valve.” Applicant respectfully submits that this unsupported conclusion is also inconsistent with the Declaration under 37 C.F.R. § 1.132, which represents the understanding of Moe et al. by one of skill in the art, and that the Examiner has not provided evidence sufficient to support a position contrary to the understanding of one skilled in the art.

In view of the foregoing, Applicant respectfully submits that one of skill in the art would not have combined these references in the manner suggested by the Office Action. Furthermore, Applicant respectfully submits that, even taken together, Moe et al. and Verona fail to disclose or suggest “a biological prosthesis comprising a substantially intact aortic valve obtained from an animal, through which substantially intact aortic valve blood flows in a single direction, the substantially intact aortic valve having a tubular outer wall, and at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of said substantially intact aortic valve, the rod penetrating the thickness of the tubular outer wall of said substantially

intact aortic valve,” as recited in independent Claim 21. Allowance of independent Claim 21 is therefore respectfully requested.

Dependent Claims 22-35

Consistent with the above-noted amendment to independent Claim 21, Claims 22, 24, 25 and 34 have also been amended to recite “the substantially intact aortic valve.”

Claims 22-35 depend, directly or indirectly, from independent Claim 21 and each recites a unique combination of features not taught or suggested by the cited art. Applicant submits that these claims are patentable for at least the same reasons that the claim from which they depend is patentable over the applied art. Applicant further submits that the cited references Rosen (cited as teaching a heart valve with commissure points), Gupta (cited as teaching heart valves coated with fluoropolymer), and Pavcnik (cited as teaching helical-shaped implants) include no teachings overcoming the above-noted deficiencies in Moe et al. and Verona. Allowance of Claims 22-35 is therefore respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: 10/550,297
Filing Date: September 21, 2005

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
LEMAN.002APC	11/814,155	INTRAPARIETAL REINFORCING DEVICE FOR BIOLOGICAL CARDIAC PROSTHESIS AND REINFORCED BIOLOGICAL HEART VALVE PROSTHESIS	July 17, 2007
LEMAN.003AUS	11/775,043	REINFORCEMENT DEVICE FOR A BIOLOGICAL VALVE AND REINFORCED BIOLOGICAL VALVE	July 9, 2007

CONCLUSION

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art discloses or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

Any remarks in support of patentability of one claim should not be imputed to any other claim in this or a related application, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant has not presented all arguments concerning whether the applied references can be properly combined in view of the clearly missing elements noted above, and Applicant reserves the right to later contest whether a proper reason exists to combine these references.

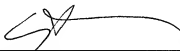
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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